

REMARKS

The Office Action of November 30, 2004 presents the examination of claims 1-25. Claims 9-19 and 22-25 have been canceled, being directed to withdrawn, nonelected subject matter. Applicants reserve the right to file an application directed to this subject matter under 35 USC § 120.

The present paper amends claims 1, 5, 6 and 21 and adds new claims 26-34.

Objections to the claims

Claims 1-8 and 21 were objected to as the naming of the bacillus was not completely spelled out and the font format was deemed incorrect. Claims 1-8 and 21 are amended to spell *Bacillus* and name the organism in italic font.

Claim 21 is further objected to as incorrectly naming the species *cylindrica*. This is addressed by amendment of claim 21.

Rejection under 35 USC § 101

Claims 1 and 3-8 are rejected under 35 USC § 101 as being directed to a natural product and thus not patentable subject matter. Claims 1 and 3-8 are amended to now recite that the claimed protein is "isolated" as required by the Examiner. New claims 26-34 are directed to a method for inhibiting anthrax toxin, and thus are also directed to statutory subject matter.

Rejection under 35 USC § 102

Claims 1-8 and 21 are rejected under 35 USC § 102 as being anticipated by Bijli et al. (2003, incorrectly cited as "Bijl" on form PTO-892) (§ 102(a)), Bijli et al. (2002, incorrectly cited as "Bijl" on form PTO-892) (§ 102(b)) or by Verma et al. (§ 102(b)). These rejections are traversed in light of the amendment of claims 1-8 and 21.

It is not clear from their data that either Bijli or Verma obtain an "isolated" protein. Compare Fig. 1(b) of the present application with Fig. 3 of Verma, showing a broad band of molecular weight $\cong 60$ to > 90 kilodaltons in lane 2 in contrast to the sharp band of 67 kDa in the immunoblot in lane 3. Also compare Fig. 1 of Bijli (2003) to Fig 1(b) of the specification.

This rejection should not apply to new claims 26-34. Neither of the Bijli references nor the Verma reference discloses any protein that may be contacted with the toxin of *Bacillus anthracis* ("anthrax") so as to inhibit the toxin activity of anthrax. None of the cited references in any way suggest that such is possible.

Thus, the invention as presently claimed is both novel and unobvious in view of the cited references and the present rejection should be withdrawn.

Rejections under 112, first paragraph

Claims 1-8 and 21 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of adequate written description and enablement of the claimed invention. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested in light of the amendments to the claims.

The Examiner simply asserts that the present invention may only be claimed in a scope that is restricted to the working examples. Such is not required by the patent laws and the instant rejections are not tenable.

As to the written description rejection, Applicants submit that the specification very well describes the invention in generic form. The general structural and functional characteristics of the protein are set forth in detail, as are a number of plant genera and species from which the protein of the invention may be obtained. The Examiner may not on the one hand say that the generic characteristics of the claimed invention, which are as set forth in the specification, recited in the claims are not sufficient to clearly distinguish what the invention is from other proteins, and then at the same time assert that such generic characteristics are sufficient to establish that the protein so described inherently possesses certain biological activities.

Applicants submit that the specification describes the invention in terms that are commensurate with the claims and that

clearly recite the generic structural and physical characteristics of the protein used in the invention, together with the activity associated with those properties. Accordingly, there is adequate written description of the claimed invention in the specification.

As to enablement, again the Examiner is trying to restrict Applicants' claims only to the scope of the working example provided. The question of enablement is one of whether or not undue experimentation is required to practice the invention throughout its scope. The key word is not "experimentation" but rather "undue". See, *In re Wands*.

The specification provides more than adequate guidance for making and using the invention as presently claimed.

First, the specification describes several plants, by genus and species, that can be used as starting materials for obtaining the protein to be used in the invention. See page 6, lines 23-26. Furthermore, the proteins of the invention isolated from the named plants are demonstrated to be immunologically cross-reactive (See, page 6, lines 23-26 and Figure 3a). Second, the specification provides a detailed protocol for extracting the effective protein (Examples 2-4 at page 11) and also detailed biochemical tests for the activities the protein is to exhibit (Examples 5-7 at page 12). Thus, there is explicit guidance provided to the skilled artisan to make and use the invention.

The Examiner appears to rely heavily upon unpredictability in the art to plead his case. The Examiner should consider however, that it is the expectation in the art of molecular biology, that embodiments of an invention will likely have to be subjected to some kind of screening test for relevant biological activities. Experimentation that is both expected and well-directed, as in the present instance, is not undue. See again, *In re Wands*.

As no undue experimentation is required to practice the invention as instantly claimed, the rejection under 35 USC § 112, first paragraph for lack of enablement by the specification, should be withdrawn.

The present application well-describes and claims patentable subject matter. The favorable action of allowance of the pending claims and passage of the application to issue is respectfully requested.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), Applicants respectfully petition for a two (2) month extension of time for filing a response in connection with the present application. The required fee of \$450.00 is attached hereto.

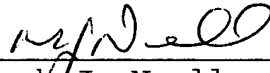
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell (Reg. No. 36,623) at the telephone number of the undersigned below, to conduct an interview

in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 
Mark J. Nuell, #36,623

DRN/mua
2761-0169P

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

Attachment(s) :